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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,224	11/06/2001	Isaac B. Horton III	1300-015	6966

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,224

Applicant(s)

HORTON, ISAAC B.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/06/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This general action is in response to the application filing date of 11/06/2001

Claim Objections

1. Claim 58 is objected to because of the following informalities:

Claim 58 was recited as being dependent on itself. Claim 58 is assumed to depend on claim 39 in examining the instant claims. Appropriate correction is required.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In claim 2, applicant recites the phrase "light pump"; however, the specification does not disclose such a feature.

In claim 7, applicant recites the phrase "electrodeless lamp"; however, the specification does not disclose such a feature.

In claim 9, applicant recites the term "UVV"; however, the specification does not disclose such a feature.

In claim 39, applicant recites the phrase "dose region"; however, the specification does not disclose such a feature.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 9-17, 19-27, 33, 35-39, 41-49, 55 and 57-61 are rejected under 35 U.S.C. 102(e) as being anticipated by DiStefano (Pub. No. US 2003/0045868 A1).

With respect to claims 1, 39 and 61, the DiStefano reference discloses the following: a blood purifier (made up of 12, 32 and other components of the device), light source (52 within 50) connected to quartz optical fiber connection (54) that inherently provides a focused and controllable light output (optical fibers include transparent material that transmits light by repeated internal reflections) to a blood purifier (made up of 12 and 32 and other components of the device), inherent control means in order to produce the required UV dose (paragraph 0016), UV dose zone (the area where UV light is applied to from the tip of optic fiber 32), housing (50), dose region (is the inherent intensity of UV light that is applied within the dose region), a method of sterilizing blood (paragraph 0004, lines 11-14 and paragraph 0013), activating UV light source (inherent step for the sterilization of blood to occur) and passing the blood through the blood purifier (when the needle is pushed into the vein, blood will inherently move or pass through the dose zone of the blood purifier created by 32 upon activation of the device).

With respect to claims 2-4, 9-17, 19-27, 33, 35-38, 41-49, 55 and 57-60, the DiStefano reference teaches the following: light pump (50, 52, 54 and an inherent power supply), a UV lamp that emits light in the UVV and UVC wavelengths (52 and paragraph 0016), light source optical component that is UV transmissive and UV reflective (54

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such that bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), fiber optic transmission line (54 that include glass lines) is removably connectable to light source and the blood purifier (figure 4 includes two nuts where the first 56 and the second is unlabeled that connect 54 to both the light source and the blood purifier), blood purifier includes dose zone and a housing (the area where UV light is applied to from the tip of optic fiber 32 and 50), dose zone includes a portal (56) for removable connection to fiber optic transmission line (54), portal optical component positioned between the portal opening and the interior of the blood purifier (the fiber optic 54 contains glasses that reflect UV light within the bundle sheath such that any glass within 54 is a portal optical component positioned between the portal opening and the interior of the blood purifier 32), portal optical component is both UV transmissive and reflective that is made up of reflectors (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), blood purifier uses enhanced two or three dimensional design (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections such that two and three dimensional designs are inherent features of the optic fibers line), dose zone includes a delivery device (tip of 32 is equivalent to the delivery device), which represents end-emitting fiber optic transmission line, interior surface of the blood purifier is a UV reflective surface (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections), blood purifier includes one interior optical component that is attached to the interior surfaces (the interior surfaces

of 32 inherently include optical components made of glass that are attached to such surfaces) and the reflective interior optical components are both UV transmissive and reflective (bundle of quartz optic fibers includes glass or other transparent material that transmits light by repeated internal reflections).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 8, 18, 28-31, 40 and 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiStefano (Pub. No. US 2003/0045868 A1) in view of Horton et al (U.S.P.N. 6,454,937).

The teachings of the DiStefano reference have previously been set forth with respect to claims 1-4, 9-17, 19-27, 33, 35-39, 41-49, 55 and 57-61; however, with respect to claims 5, 8, 18, 28-30, 40 and 50-52, the DiStefano reference fails to teach the following: high-intensity lamp such as mercury halide lamp, the housing is UV

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reflective, the delivery device is a vertical riser configuration that is scalable to applications and the delivery device is a planar configuration. The ('937) reference, which is in the art of disinfecting fluids, teaches the following: high-intensity lamp (62) such as mercury halide lamp (the reference teaches that various types of lamps can be used in the device, col.6, lines 15-20, such that choosing a certain conventional type is a matter of choice of design), the housing is UV reflective (within 50 there is 64 as shown in figures 4-5), the delivery device is a vertical riser configuration (200) with intrinsic features, for example, predetermined blood flow rate, the VRC is scalable to applications (the reference teaches various design modification in col.7, lines 25-27, lines 47-49, lines 61-65 and col.5, lines 56-59 such that depends on the characteristics of the water being treated) and the delivery device is a planar configuration (figures 4-5). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the DiStefano reference to substitute the blood purifier with the vertical riser configuration device of the ('937) reference since the VRC creates turbulence at the top of the column that result in having the microorganisms being more effectively radiated by the UV light beam as disclosed by the ('937) reference (col.8, lines 5-7).

With respect to claims 31 and 53, the DiStefano reference teaches that the blood purifier is manufactured from quartz (54).

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiStefano (Pub. No. US 2003/0045868 A1) in view of Windham et al (U.S.P.N. 6,587,575).

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The teachings of the DiStefano reference have previously been set forth with respect to claims 1-4, 9-17, 19-27, 33, 35-39, 41-49, 55 and 57-61; however, with respect to claim 6, the DiStefano reference fail to teach the use of a spectral calibration lamp. The Windham reference, which is in the art of food treatment, teaches the use of spectral calibration lamps (col.15, lines 33-35). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the UV lamp of the DiStefano reference with the spectral calibration lamp since such a substitution is a matter of design choice as evidenced by the Windham reference.

9. Claims 7, 34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiStefano (Pub. No. US 2003/0045868 A1) in view of Danilychev (U.S.P.N. 5,931,557).

The teachings of the DiStefano reference have previously been set forth with respect to claims 1-4, 9-17, 19-27, 33, 35-39, 41-49, 55 and 57-61; however, with respect to claims 7, 34 and 56, the DiStefano reference fail to teach using electrodeless lamp and using aluminum or stainless steel as the reflective material. The Danilychev reference, which is in the art of UV light irradiation, teaches using electrodeless lamp (col.20, lines 33-34) and using aluminum or stainless steel as the reflective material (col.3, lines 24-28). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the DiStefano reference to include aluminum since such a modification is a design choice as evidenced by the Danilychev reference.

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10. Claims 32 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiStefano (Pub. No. US 2003/0045868 A1) in view of Horton et al (U.S.P.N. 6,454,937) and further in view of Goss (U.S.P.N. 4,705,498).

The teachings of the DiStefano reference have previously been set forth with respect to claims 1-4, 9-17, 19-27, 33, 35-39, 41-49, 55 and 57-61; however, with respect to claims 32 and 54, both the DiStefano reference and the ('937) reference fail to teach the concept of a disposable blood purifier. Figure 1, 20 in the instant application shows the blood purifier as the treatment chamber. The Goss reference, which is in the art of irradiating biological fluids, teaches the concept of having a disposable irradiation chambers (col.1, lines 15-17). Thus, Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the DiStefano reference to include a disposable blood purifier as taught by the Goss reference in order to maintain sterility of the procedure (col.10, lines 40-44 and lines 57-62).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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